K133731

MAY 0 8 2014

A.4. 510(k) Summary

Submitted by:	Phuong Nguyen Senior Regulatory Affairs Manager Nobel Biocare USA LLC 22715 Savi Ranch Parkway Yorba Linda, CA 92887
Submitted for:	Nobel Biocare AB Vastra Hamngatan 1 Goteborg, SE 411 17 Sweden
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Date of Submission:	December 5, 2013
Classification Name: Product Code:	Endosseous Dental Implant (21 CFR 872.3640) DZE, NHA
Trade or Proprietary or Model Name:	NobelActive Wide Platform (WP)
Legally Marketed Devices:	Nobel Biocare – NobelActive Internal Connection Implant (K071370) Nobel Biocare – NobelProcera PEEK Abutments (K120954) Nobel Biocare – NobelProcera Ti Abutments (K091756) Nobel Biocare – NobelSpeedy Implants (K050406) Nobel Biocare – NobelActive 8.5 mm & 18.0 mm (K083205)

Device Description:
Nobel Biocare's NobelActive Wide Platform (WP) implants are threaded, root-form dental implants intended for use in the upper and/or lower jaw to support prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function to partially or fully edentulous patients. They are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

The NobelActive Wide Platform (WP) implants share the same basic design principles as the existing NobelActive Internal Connection Implant. The Wide Platform (WP) implants are a bigger diameter implant extending the range of the existing NobelActive platforms. The Wide Platform is made of commercial pure titanium, is 5.5 mm in diameter, and available in lengths from 6.5 mm to 12.5 mm.

Healing and temporary abutments in both titanium/vanadium alloy and PEEK and definitive abutments made of titanium/vanadium alloy are available for the new WP platform. Titanium abutments may also be designed and made individually to fit the individual requirements for each patient using NobelBiocare's NobelProcera system.

Indications for Use:
Nobel Biocare's NobelActive implants are endosseous implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare's

NobelActive implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare's NobelActive implants are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Summary of testing to demonstrate Substantial Equivalence

Nobel Biocare utilizes an ISO 14971 Risk Management System. The NobelActive Wide Platform (WP) was subjected to this system which determined that no clinical or non-clinical test data was necessary to support the decision of safety and effectiveness excluding the MRI Safety and compatibility. MR conditional testing was conducted according to FDA Guidance Document "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment".

Modifications were made to the NobelActive product labeling to include the Wide Platform.

Conclusion

The information provided in this submission demonstrates that the device is substantially equivalent to the predicate devices.

Technological Characteristics
(Part 1 – Implant)

	CANDIDATE	PREDICATE	PREDICATE	PREDICATE
	NobelActive Wide Platform (WP)	NobelActive Internal Connection Implant (K071370)	NobelActive 8.5 mm & 18.0 mm (K083205)	NobelSpeedy Implants (K050406)
Thread Design	**Double lead thread** **Reverse cutting flutes**	Double lead thread Reverse cutting flutes	Double lead thread Reverse cutting flutes	Single lead thread
Implant Body Design	**Expanding Taper** **Drilling blades on apex**	Expanding Taper Drilling blades on apex	Expanding Taper Drilling blades on apex	Tapered apex with bone cutting flutes
Implant Body Length	**6.5, 8, 9.5, 11, 12.5 mm**	9.5, 11, 12.5 mm	8, 17.5 mm	6.5, 8, 9.5, 11, 12.5, 14.5, 17.5 mm
Overall Length	**6.5, 8, 9.5, 11, 12.5 mm**	9.5, 11, 12.5 mm	8, 17.5 mm	7, 8.5, 10, 11.5, 13, 15, 18 mm
Implant Width	**5.5 mm**	3.5, 4.3, 5 mm	3.5, 4.3, 5 mm	3.5, 4.0, 5.0, 6.0 mm
Connection Type	**Internal Hex**	Internal Hex	Internal Hex	External Hex
Device Material	**CP Titanium**	CP Titanium	CP Titanium	CP Titanium
Surface	**TiUnite**	TiUnite	TiUnite	TiUnite
Labeling	**MR Safety Information** **Section Implant specification additional warning related to short Implants**	No MR Safety information No additional warnings regarding short implants	No MR Safety information No additional warnings regarding short implants	No MR Safety information No additional warnings regarding short implants

Technological Characteristics

(Part 2 – Abutments)

	CANDIDATE	PREDICATE	PREDICATE	PREDICATE
	NobelActive Wide Platform (WP)	NobelActive Internal Connection Implant (K071370)	NobelProcera PEEK Abutments (K120954)	NobelProcera Ti Abutments (K091756)
Material	**Titanium/vanadium alloy PEEK**	Titanium/vanadium alloy	PEEK	Titanium/vanadium alloy
Intended Use	**Definitive restorations Provisional restorations**	Definitive restorations Provisional restorations	Provisional restorations	Definitive restorations
Design Method	**Standardized design Patient specific design**	Standardized design	Standardized design Patient specific design	Patient specific design
Platform	**Internal Hex 5.5 mm**	Internal Hex 3.5, 4.3, 5 mm	Internal Hex 3.5, 4.3, 5 mm External Hex 3.5, 4, 5 mm Internal Tri-Lobe 3.5, 4.3, 5, 6 mm	Internal Hex 3.5, 4.3, 5 mm External Hex 3.5, 4, 5 mm Internal Tri-Lobe 3.5, 4.3, 5, 6 mm Various third party platforms

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 8, 2014

Nobel Biocare AB
C/O Ms. Phuong Nguyen
Senior Regulatory Affairs Manager
Nobel Biocare USA, Limited Liability Company
22715 Savi Ranch Parkway
Yorba Linda, CA 92887

Re: K133731
Trade/Device Name: NobelActive Wide Platform (WP)
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: March 5, 2014
Received: March 7, 2014

Dear Ms. Nguyen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A.3.

Indications for Use

510(k) Number (if known): K133731

Device Name: **NobelActive Wide Platform (WP)**

Indications For Use:

Nobel Biocare's NobelActive implants are endosseous implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare's NobelActive implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare's NobelActive implants are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
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